

REMARKS

After entry of this amendment, claims 1, 5-10, 12-15, and 17-26 are pending, of which claim 15 is withdrawn. The claims have been amended or cancelled without disclaimer or prejudice. Support for the amendments is found *inter alia* in the original claims. Amended claim 1 finds support in original claims 1, 2, 4, and 6, in the specification at page 2 lines 15 and 29, page 4 List 1 row 2, page 9 lines 17-21, page 14 lines 1-5, and in Example 8 at page 41. The non-elected subject matter from claims 5 and 6 has been deleted without prejudice or disclaimer. The amendments to claims 10 find support in original claims 2 and 10, and in the specification at page 2 lines 15 and 29, and page 4 lines 17-18. The amendments to claim 15 find support in the specification at page 6, lines 11-23, and in original claims 15 and 16. Claims 2-4, 11, and 16 have been cancelled without prejudice or disclaimer. Non-elected claims and subject matter are cancelled without prejudice or disclaimer. New claims 17-26 find support in the original claims and in the specification at page 4 lines 29-31, and page 11 lines 28-33. The new claims are consistent with the restriction requirement. No new matter has been added.

In the amendment to the specification, the heading and associated paragraph referencing the related applications already of record and a Brief Description of the Figures have been added. Support for the brief description of Figure 1 is found in the specification at page 26, line 20, and page 33, lines 33-34; for Figure 2 at page 26, line 21, and at page 35, lines 9-11; and for Figure 3 at page 26, line 22, and at page 40, lines 29-30. No new matter has been added.

Claim Objections

The Examiner objects to claims 4, 5, and 6 for reciting non-elected subject matter. In light of the amendments, the objection is believed to be rendered moot and is respectfully requested to be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner rejects claims 1-4 and 7-14 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement and on the basis that the

specification does not provide an enabling disclosure. Applicants respectfully disagree and traverse the rejections for the following reasons.

Written Description

The Examiner argues that the specification fails to describe the structure and function of all DNA sequences from any source that are capable of encoding a protein with metY activity. The Examiner further argues that the recitation of SEQ ID NO: 1, 3, 5, ..., 51 and 53 encoding a protein with metY activity is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Applicants respectfully disagree, but in order to expedite prosecution, the claims have been amended without prejudice or disclaimer to recite a specific-sulfur containing chemical "L-methionine" and, in one embodiment, an additional gene of the "L-methionine" pathway.

The applicable test for written description is stated in the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1, Written Description Requirements" 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001). As there indicated, the written description requirement for a claimed genus can be satisfied in a number of alternative ways, such as through sufficient description of a representative number of species by actual reduction to practice, by disclosure of relevant identifying characteristics, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics.

The Examiner asserts that the specification does not teach the structure or function of all DNA sequences capable of encoding a protein with metY activity. In response, there has never been a requirement that every species encompassed by a claim must be disclosed or exemplified in a working example. *In re Angstadt*, 537 F.2d 498 (CCPA 1976). Applicants have provided the structure of twenty-seven polynucleotides as set forth in SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, 49, 51, and 53. The twenty-seven polynucleotides are further characterized as each encoding a protein with metY activity. Applicants urge that twenty-seven polynucleotides encoding a protein with metY activity

constitutes a representative number of species, particularly considering that the claims as amended recite production of L-methionine.

Furthermore, Example 18 of the "Synopsis of Application of Written Description Guidelines" is particularly relevant, since the claims of the present invention are drawn to methods and not to polynucleotides. The claims in Example 18 of the Guidelines relate to a method of producing a protein and are drawn to a genus, *i.e.* any of a number of methods that can be used for expressing protein in mitochondria of the organism. Furthermore the recitation of a specific nucleic acid was not essential to the method. There was actual reduction to practice of a single embodiment, and there was no substantial variation within the claimed genus because there are a limited number of ways to practice the process steps.

Similar to Example 18, the present specification describes production of L-methionine by fermenting coryneform bacteria expressing a nucleotide sequence which encodes a protein with metY activity. The present specification also describes an embodiment of the method in which a further gene in the L-methionine biosynthetic pathway is overexpressed or mutated. Additionally, as in Example 18 of the Guidelines, the present specification provides an actual reduction to practice of the method as shown in Example 8. In Example 8, clones, which comprise a nucleotide sequence encoding the protein with metY activity and an additional mutated gene in the L-methionine biosynthetic pathway, were cultured in fermentation, and the desired production of the protein resulted. That process is the same irrespective of the selection of the polynucleotide sequence encoding a metY protein or of the gene in the pathway. As in Example 18 of the Guidelines, the present claims are adequately described.

The present specification shows a representative number of species having metY activity, and establishes a connection between a coryneform bacterium containing such a gene and production of L-methionine. For these reasons, it is submitted that the claims as amended are in compliance with the written description requirement. Reconsideration and withdrawal of this rejection is respectfully requested.

Enablement Rejection

The Examiner asserts that the specification does not provide enablement for producing any sulfur containing chemical, for any polynucleotide encoding a protein with metY activity. Applicants respectfully disagree. However in order to expedite prosecution, the claims have been amended without disclaimer or prejudice and call for production of L-methionine. Furthermore, the specification and the Examples have shown that expression of a metY protein in a coryneform bacteria increases L-methionine. (See, for example, Example 8 at page 41).

The Examiner further alleges that the scope of the claims is not commensurate with the enablement provided by the disclosure based on what mutations or modifications would be required and the lack of knowledge of the structure/function relationship for such modifications. In response, the claims as amended call for a protein with metY activity having at least 95% or more homology to SEQ ID NO: 4 or for a nucleotide sequence having at least 95% or more identity to SEQ ID NO: 3 encoding a protein with metY activity.

In summary, the specification discloses twenty-seven exemplary polynucleotides workable in the claimed process. Furthermore, the sulfur-containing fine chemical and pathway are specified as L-methionine. Additionally, the Examples have shown that expression of a metY protein in a coryneform bacteria increases L-methionine. This extensive disclosure provides guidance and working examples for the skilled artisan to practice the full scope of the process as now claimed.

For these reasons and in light of the amendments, reconsideration and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 102(b)

Claims 1-3 and 7-14 were rejected as being anticipated by any one of WO 02/18613 (hereinafter "Degussa I"), WO 02/10206 (hereinafter "Degussa II"), or WO 02/10209 (hereinafter "Degussa III"). Applicants respectfully traverse.

The Examiner characterizes Degussa I as disclosing production of fine chemicals by fermentative preparation using a metY gene from *Corynebacterium glutamicum*, and other polynucleotides sequences which are at least 70% identical encoding the metY of SEQ ID NO: 2.

Claim 1 as amended in the present application recites a metY protein having the sequence of SEQ ID NO: 4 or a variant with 95% homology to SEQ ID NO: 4. SEQ ID NO: 2 of Degussa I has 437 amino acids, whereas SEQ ID NO: 4 of the present application has 449 amino acids. New claim 20 recites that the metY protein is encoded by the nucleotide sequence of SEQ ID NO: 3 or a variant with 95% identity to SEQ ID NO: 3. The Examiner has acknowledged that SEQ ID NO: 3 is free of prior art. SEQ ID NO: 3 and 4 of the present application are from *Mycobacterium tuberculosis*. Thus, the metY disclosed in Degussa I is different than the metY required by all the claims of the present application. Therefore, Degussa I does not disclose every limitation of the claims and does not anticipate the claims.

The Examiner has also rejected claims 1-3 and 7-14 as being anticipated by Degussa II. Applicants respectfully traverse that Degussa II anticipates any currently pending claims. The Examiner has not provided any separate arguments relating to Degussa II. Degussa II discloses the sequence of a metF (SEQ ID NO: 2) having 349 amino acid residues from *Corynebacterium glutamicum*, whereas the metY of the present application has 449 amino acids. Moreover, Degussa II relates to polynucleotides and methods which relate to metF. The metF gene encodes methylenetetrahydrofolate reductase while the metY gene of the present application encodes O-acetylhomoserine sulphydrolase. MetF and metY have different activities, different sequences, and catalyze different reactions. Additionally, the Examiner has acknowledged that SEQ ID NO: 3 is free of prior art. Because Degussa II does not disclose every limitation of the present claims, Degussa II also does not anticipate the claims.

Additionally, the Examiner has rejected claims 1-3 and 7-14 as being anticipated by Degussa III. Applicants respectfully traverse that Degussa III anticipates any currently pending claims. The Examiner has not provided any separate arguments relating to Degussa III. Degussa III discloses the sequence of a metH (SEQ ID NO: 2) having 1221 amino acid residues from *Corynebacterium glutamicum*, whereas the metY of the present application has 449 amino acids.

Moreover, Degussa III relates to polynucleotides and methods which relate to metH. The metH gene encodes homocysteine methyltransferase II while the metY gene encodes O-acetylhomoserine sulphydrolase. MetH and metY have different activities, different sequences, and catalyze different reactions. Additionally, the Examiner has acknowledged that SEQ ID NO: 3 is free of prior art. Because Degussa III does not disclose every limitation of the present claims, Degussa III does not anticipate the claims.

Because the sequences and methods disclosed in Degussa I, Degussa II, and Degussa III are different than those claimed in the present invention, none of the Degussa references disclose every limitation of the claims. Therefore, none of the Degussa references anticipates the claims. Reconsideration and withdrawal of this rejection is respectfully requested.

Furthermore, Applicants note that the Examiner appears to have examined the method for preparation of animal feed additive (see Official Action at page 8), as recited in claim 15. Furthermore, claim 15 has been amended encompassing a fermentation step similar to that of claim 1. No further search would be required as a search of the subject matter of claim 15 would overlap with the search already done for claim 1. Accordingly, Applicants respectfully request rejoinder of claim 15 as amended.

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications, if necessary.


Applicants wish to inform the Examiner that co-pending applications Serial No. 10/525,907 and Serial No. 10/525,674 have been allowed.

Application No.: 10/525,710
Amendment dated August 14, 2007
Reply to Office Action of May 14, 2007

Docket No.: 13111-00006-US

This response is filed within the three month period for response from the mailing of the Office Communication, to and including August 14, 2007. A fee sheet authorizing payment for the new claims is enclosed. No further fee is believed due. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 13111-00006-US from which the undersigned is authorized to draw.

Respectfully submitted,

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